120 (2)

No. 08-889

Supreme Court, U.S.
FILED
FEB 17 2009
OFFICE OF THE CLERK

In The Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF *AMICUS CURIAE* NATIONAL FISHERIES INSTITUTE IN SUPPORT OF PETITIONER TRI-UNION SEAFOODS' PETITION FOR WRIT OF *CERTIORARI*

AKIN GUMP STRAUSS HAUER & FELD LLP

REX S. HEINKE
(*Counsel of Record*)
JESSICA M. WEISEL
2029 Century Park East,
Suite 2400
Los Angeles, California
90067-3012
Telephone: 310-229-1000
Facsimile: 310-229-1001

WARREN E. CONNELLY
Robert S. Strauss Building
1333 New Hampshire
Avenue, N.W.
Washington, DC
20036-1564
Telephone: 202-887-4000
Facsimile: 202-887-4288

Attorneys for Amicus Curiae,
National Fisheries Institute

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

	Page
INTEREST OF *AMICUS CURIAE*	1
REASONS WHY THE PETITION SHOULD BE GRANTED	3
I. The Third Circuit Opinion Raises Important Questions That Have A Broad-Reaching Effect On The Seafood Industry And The Public Health	4
A. The FDA Has Deliberately Chosen To Rely On Advisories Instead Of Warning Labels To Educate The Public About The Benefits And Potential Risks Of Consuming Fish And Shellfish	4
B. The Third Circuit Opinion Mandates An Unworkable State Regulatory Scheme	11
C. The Third Circuit Opinion Subjects Consumers To Economic Harm, Deprives Them Of Health Benefits, And Creates Confusion	13
D. The Third Circuit Opinion Leaves The Seafood Industry Open To Conflicting Liabilities Under State And Federal Law	15
II. The Conflict Between The Third Circuit And California Supreme Court Creates Confusion About What Law Controls In Different Jurisdictions	17
CONCLUSION	18

TABLE OF AUTHORITIES

Page

CASES

Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1 (Cal. 2004).....3, 14, 15, 16, 17

STATUTES

N.J.S.A. 2A:58C-2.....9

N.J.S.A. 2A:58C-4.....10

RULES AND REGULATIONS

Cal. Code Regs., tit. 22, § 12601 .....11, 14

S. Ct. R. 10.....3, 4

FEDERAL AGENCY MATERIALS

Draft Risk and Benefit Assessment Report: Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population (Jan. 15, 2009), http://www.cfsan.fda.gov/~dms/mehgrb.html 5, 6

Letter to Bill Lockyer, Attorney General of the State of California, from Lester M. Crawford, Commissioner of Food and Drugs dated Aug. 12, 2005, http://www.cfsan.fda.gov/~dms/fl-ltr65.html 16

TABLE OF AUTHORITIES – Continued

Page

Letter to Martin J. Hahn, Hogan & Hartson, LLP from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf ..... *passim*

NMFS, Fisheries of the United States 2007 (July 2008), http://www.st.nmfs.noaa.gov/st1/fus/fus07/fus_2007.pdf 2

What You Need to Know About Mercury in Fish and Shellfish, 2004 EPA-823-R-04-005 (March 2004), http://www.cfsan.fda.gov/~dms/admehg3.html 4, 6, 12

INTEREST OF *AMICUS CURIAE*

The National Fisheries Institute ("NFI"), headquartered in McLean, Virginia, is a non-profit organization dedicated to educating the public about seafood safety, nutrition, and sustainability.[1] The NFI's membership consists of approximately 400 seafood producers, importers, wholesalers, retailers, grocery stores, and restaurant chains, including companies such as Bumble Bee Foods, StarKist, Gorton's, Darden Restaurants, and Long John Silver's. The NFI promotes adherence to the Dietary Guidelines for Americans jointly issued by the Department of Health and Human Services and Department of Agriculture that suggest that Americans should eat fish and shellfish twice per week to reduce the risk of mortality from coronary heart disease. Among the most popular seafood items that the NFI's members catch, grow, process, distribute, and sell are tuna, shrimp, catfish, salmon, crab, and tilapia. Thus, its members have a vital interest in ensuring that the distribution of healthy and nutritious seafood to consumers is not hampered by state regulations that

---

[1] Tri-Union, the petitioner in this action, is one of several hundred members of the NFI, as is a sister corporation, Empress International Ltd. This *amicus* brief was funded entirely by the NFI out of its regular operating funds. No additional funds were contributed by Tri-Union or any other person or entity for the purpose of preparing this *amicus* brief. The NFI requested and received written consent to the filing of this brief of *amicus curiae*, as reflected in the concurrently filed letters from petitioners' and respondents' counsel.

impose complex, confusing, inconsistent, and potentially illegal warning label obligations that interfere with the carefully considered approach to seafood health and safety that the Food and Drug Administration has developed over the course of the past two decades.

The fish and shellfish industry is a major contributor to the United States economy. According to a 2008 report from the National Marine Fisheries Service ("NMFS"), "[b]y producing and marketing a variety of fishery products for domestic and foreign markets, the commercial marine fishing industry contributed $34.2 billion (in value added) to the U.S. Gross National Product." NMFS, Fisheries of the United States 2007 (July 2008), http://www.st.nmfs.noaa.gov/st1/fus/fus07/fus_2007.pdf, at v. Domestic consumers spent $68.4 billion on seafood in 2007, consuming a *per capita* average of 16.3 pounds of fish and shellfish in that year. *Id.* at iv-v.

The NFI submits this *amicus* brief in support of Tri-Union's Petition because the practical effect of the Third Circuit's opinion is to impose a nearly impossible compliance burden on thousands of domestic seafood producers and sellers. Specifically, to avoid the possibility of incurring significant liability for damages in private state actions, they must place methylmercury warning labels on virtually all of their fish and shellfish products, not just their tuna products, because those products all contain some amount of methylmercury. The Third Circuit would require these warnings even though the FDA has

stated that they are inherently incapable of providing the sophisticated and nuanced advice that the agency has developed over the years through a series of advisories issued under the federal Food, Drug and Cosmetics Act ("FDCA"). The opinion also subjects seafood sellers to great uncertainty and huge potential expense if they must comply with widely varying state laws governing what seafood sellers should and should not say in warnings about methylmercury levels.

REASONS WHY THE PETITION SHOULD BE GRANTED

Tri-Union's Petition identifies two separate grounds for *certiorari*: (1) the Third Circuit opinion raises an important question of federal law that this Court should settle, namely, whether the FDA's deliberate decision not to require consumer warnings for methylmercury in seafood should be given pre-emptive effect to avoid the chaos and burden that would result from inconsistent and conflicting state law warning label requirements; and (2) the opinion directly conflicts with the opinion of the California Supreme Court in *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004), which held that the FDCA would preempt state law warning requirements like the ones that seafood suppliers would have to adopt to avoid liability under the New Jersey laws discussed in the Third Circuit opinion. S. Ct. R. 10(c) (the Court considers whether "a United States court of appeals has decided an important

question of federal law that has not been, but should be, settled by this Court"); S. Ct. R. 10(a) (the Court considers whether a United States court of appeals "has decided an important federal question in a way that conflicts with a decision by a state court of last resort"). *Certiorari* should be granted to settle the law, which has grave ramifications for the seafood industry as well as for consumer health, and to resolve the conflict.

I. The Third Circuit Opinion Raises Important Questions That Have A Broad-Reaching Effect On The Seafood Industry And The Public Health.

A. The FDA Has Deliberately Chosen To Rely On Advisories Instead Of Warning Labels To Educate The Public About The Benefits And Potential Risks Of Consuming Fish And Shellfish.

The benefits of eating fish and shellfish are well-established. In its most recent consumer advisory, entitled *What You Need to Know About Mercury in Fish and Shellfish*, 2004 EPA-823-R-04-005 (March 2004), http://www.cfsan.fda.gov/~dms/admehg3.html ("2004 Advisory"), the FDA summarized these important benefits as follows:

> Fish and shellfish are an important part of a healthy diet. Fish and shellfish contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids. A well-balanced diet that

> includes a variety of fish and shellfish can contribute to heart health and children's proper growth and development. So, women and young children in particular should include fish or shellfish in their diets due to the many nutritional benefits.

In addition, the FDA has just published a draft report that reinforces the 2004 Advisory:

> Fish provides protein, is low in saturated fat, and is rich in many micronutrients; it also can be a source of certain omega-3 fatty acids. As the Institute of Medicine of the National Academies of Science (IOM) noted in a recent report, "[i]n the past several years, research has implicated seafood, particularly its contribution of EPA and DHA [two omega-3 fatty acids], in various health benefits identified for the developing fetus and infants, and also for adults, including those at risk for cardiovascular disease" (IOM 2006 at 1).

Draft Risk and Benefit Assessment Report: Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population (Jan. 15, 2009), http://www.cfsan.fda.gov/~dms/mehgrb.html ("2009 Draft Report").

Although the FDA recognizes the potential risk of excessive methylmercury consumption by pregnant

women, women who intend to become pregnant, nursing mothers, and young children, the FDA nonetheless concludes that "consumption of fish species that are low in methylmercury has a significantly greater probability of resulting in a net benefit, as measured by verbal development [in children]." 2009 Draft Report at 3. Moreover, "[f]or fatal coronary heart disease and stroke, commercial fish baseline consumption is averting a central estimate of over 30,000 deaths per year from coronary heart disease and over 20,000 deaths per year from stroke." *Id.*

To address the risks to those consumers that could possibly develop health problems due to high levels of methylmercury exposure, the FDA has issued targeted advisories that provide specific information about the types of fish and shellfish that are safe to eat and those that should be avoided. Letter to Martin J. Hahn, Hogan & Hartson, LLP from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf at 28, n.71 ("FDA Martek Petition Denial") (describing targeting mailings from the FDA to obstetricians and gynecologists, as well as efforts to use women's magazines and professional health organizations to spread information to the target populations). These advisories educate consumers about the amounts of different types of seafood that are safe for consumption. *See, e.g.*, 2004 Advisory. The FDA has concluded that these advisories are the best way to educate the public and protect those most at

potential risk of developing methylmercury-related health problems, while also ensuring that the public is not deterred from consuming fish and shellfish. FDA Martek Petition Denial at 28-29.

The FDA deliberately decided to rely on advisories and communications through physician's offices, and not to require product warnings about methylmercury to be placed: (1) on every package of tuna and other mercury-containing seafood; (2) at every grocery store fish counter; and (3) on every restaurant menu. In rejecting a petition seeking to impose point of sale product-specific methylmercury warnings, the FDA explained that they do not and cannot contain the "level of clarity and detail" necessary to explain the types of seafood that people should and should not eat, and their appropriate serving sizes, because there is insufficient space on a product label. FDA Martek Petition Denial at 29. The FDA further warned of confusion "when different kinds of label statements are put on different species of commercial fish and not on locally caught fish." *Id.*

In addition, the FDA recognized that warnings might deter consumers outside the at-risk groups from eating any seafood, which would result in loss of the significant health benefits associated with seafood consumption:

> [A] label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results suggest that people who are not in the target audience (*i.e.*, women who are not

> nursing and not likely to become pregnant, and men) might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish and possible harmful health effects to pregnant women, women who might become pregnant, nursing mothers, and young children (ORC Macro, 2003). Therefore, the statement about possible harmful effects of mercury accompanying the qualified health claim would likely have the effect of negating the qualified health claim.

FDA Martek Petition Denial at 29. Thus, the FDA has selected detailed advisories instead of necessarily abbreviated point of sale product-specific warning labels as the appropriate method of balancing the health benefits of fish and shellfish consumption with the possible risks of exposure to methylmercury. The FDA also has chosen to distribute the advisory through physicians, who are well-suited to communicate the nuanced messages. By rejecting federal preemption of state regulation, the Third Circuit upsets this carefully tailored health and safety policy.

B. The Third Circuit Opinion Mandates An Unworkable State Regulatory Scheme.

The Third Circuit opinion affects virtually the entire fish and shellfish industry, not just sellers of canned, pouched, frozen, and fresh tuna. The 2004 Advisory states that "nearly all fish and shellfish contain traces of mercury." Consequently, every seller

of fish and shellfish is potentially subject to a product liability lawsuit under broadly written state statutes when they fail to warn in some way all consumers, not just the groups that the FDA has determined are potentially at risk, about the possible risks of consuming fish or shellfish that contain at least trace elements of methylmercury.

The New Jersey law at issue in this case illustrates the difficulty that seafood suppliers face in attempting to devise "adequate warnings" for all of their products. It states that a manufacturer or seller of a product:

> shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: . . . b. failed to contain adequate warnings or instructions.

N.J.S.A. 2A:58C-2. The statute does not define what constitutes an "adequate warning," but instead provides that:

> [a]n adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the

> persons by whom the product is intended to be used.

N.J.S.A. 2A:58C-4.

Under this statute, nearly every seafood product would require some form of methylmercury warning label or sign on its container or at the point of sale to the consumer, but the type of warning would necessarily need to vary depending on the type of product, the amount of that product being purchased at one time, as well as over time, and the demographic profile of the potential purchaser.

The Third Circuit did not recognize the complexity of New Jersey's "adequate warning" requirement. It stated that Tri-Union could have avoided liability by including a warning that "specified that the risks become material only with frequent tuna consumption, and that moderate fish consumption offers positive health benefits." Appendix to Tri-Union Petition ("App.") at 35a. However, every seafood seller – not just distributors like Tri-Union, but also, for example, grocery store chains, stand-alone fish markets, and restaurants – would need to devise warnings tailored to the type of methylmercury-containing seafood being sold. In other words, a warning for one seafood product with a negligible methylmercury content would not be "adequate" to warn of the potential risks of over-consumption of another seafood product with a relatively high

methylmercury content.[2] And, if the stronger warning was used for all seafood products, then consumers would respond by reducing their purchases of those products with negligible methylmercury content, thereby depriving themselves of the strong health benefits about which the FDA has advised consumers in its advisories.

That would just be for New Jersey. Other states have enacted product liability laws that take different positions on what constitutes an adequate consumer warning. California, for instance, contains an optional "safe harbor" provision that allows a seafood supplier to use a generic warning to comply with the state warning law requirement: "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." Cal. Code Regs., tit. 22, § 12601(b)(4)(B). It is

---

[2] This would even be true for different types of canned tuna, because, as the FDA has acknowledged, canned light tuna has a lower methylmercury content than white albacore tuna. *See* 2004 Advisory (listing "canned light tuna" as a low-mercury product, but recommending restricting consumption of white albacore tuna to no more than 6 oz. per week because it "has more mercury than canned light tuna."). Thus, if seafood suppliers must provide warnings specific to different seafood products to comply with state warning law requirements, a warning applicable to canned light tuna would not be sufficient to warn of the risks of overconsumption of canned white albacore tuna. Thus, the products would require different warnings. Alternatively, a single warning covering both types of tuna would discourage greater consumption of light tuna even though the FDA has found that greater consumption of it does not create a health risk.

difficult to see how such a warning would "communicate[ ] adequate information on the dangers and safe use of the product," as required by the New Jersey statutes, or "specif[y] that the risks become material only with frequent tuna consumption," as the Third Circuit suggested would avoid a products liability claim. This would mean that what is appropriate for California may not suffice in other states.

In summary, the Third Circuit opinion upends the careful work of the FDA by requiring the seafood industry to develop warning labels and point of sale signs for all seafood products that contain any amount of methylmercury, no matter how small, to avoid the risk of a product liability lawsuit by a consumer like Deborah Fellner, who overindulges in disregard of both common sense and the FDA's widely circulated advisories.[3] Moreover, varying state warning label requirements will require multi-state seafood suppliers to adopt a state-by-state approach to compliance, which will impose an impossible burden. In contrast, the FDA's considered analysis of scientific data and its decision about how best to protect the public will be ignored. The resulting unworkable scheme of state government regulation will substantially harm the seafood industry, making compliance with warning laws extremely difficult and driving up the costs of providing fish and shellfish to the public.

---

[3] As the Third Circuit noted, "from 1999 to 2004, [Ms. Fellner's] diet consisted almost exclusively of TriUnion's tuna products." App. at 2a.

C. The Third Circuit Opinion Subjects Consumers To Economic Harm, Deprives Them Of Health Benefits, And Creates Confusion.

The seafood industry is not alone in facing increased economic costs because of the Third Circuit's opinion. If the industry is forced to incur significant expenses to provide state-by-state warnings, some of those costs will be passed on to consumers. That could drive up the cost of seafood, which will, in turn, result in decreased consumption, along with the loss of the health benefits associated with their consumption.

Consumer confusion is another serious danger. If seafood sellers are forced to place detailed product-specific warnings on their packages, as well as at grocery store fish counters and on restaurant menus, they are likely to confuse consumers and decrease overall seafood consumption. As the FDA's focus groups demonstrated, general warnings about methylmercury deter beneficial consumption by the general public, not just the groups that are potentially at risk of methylmercury-related health problems.[4] FDA Martek Petition Denial at 28. That will adversely affect the public health, which is precisely

---

[4] An equal concern is that the groups for whom the FDA has issued targeted warnings – pregnant women, nursing mothers, and young children – may be overwhelmed by warnings and may disregard them altogether.

what the FDA sought to avoid by relying on advisories instead of warning labels.

The California "safe harbor" warning illustrates how general warnings may be counter-productive. It allows a seller to comply with the warning requirement merely by stating that a product "contains a chemical known . . . to cause birth defects or other reproductive harm." Cal. Code Regs., tit. 22, § 12601(b)(4)(B). Since all fish and shellfish contain some amount of methylmercury, a grocery store, for instance, might be able to satisfy its warning obligations by placing a single "safe harbor" warning on its seafood display case. But that would not provide information to consumers about the relative benefits and potential risks of seafood for different groups of consumers, or draw distinctions between the types of seafood that are safe for the at-risk groups to consume and those they should avoid. Instead, such a warning is likely to deter consumers from buying any seafood.

That is precisely why the California Supreme Court held the FDCA preempted California's warning law as it applied to nicotine-containing products designed to help people stop smoking. Although the "safe harbor" warning was arguably true for the smoking-cessation products, a general warning "may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision." *Dowhal*, 88 P.3d at 14. Thus, for example, the "safe harbor" warning may deter a pregnant woman from using the

smoking-cessation product, and instead continue smoking, despite its greater health risks. *Id.*

By the same logic, general warnings could deter people from consuming any seafood. While well-intended, state law warning requirements could actually hurt the public and should be preempted when the FDA has chosen instead to use a "nuanced" approach to balancing the benefits and risks of certain products (*Dowhal*, 88 P.3d at 15). Thus, allowing the Third Circuit opinion to stand unreviewed could have grave implications for the public health.

D. The Third Circuit Opinion Leaves The Seafood Industry Open To Conflicting Liabilities Under State And Federal Law.

The FDA Martek Petition Denial also highlights another significant danger of warnings – they may provide false information. Sellers of fish and shellfish may adopt unnecessary warnings simply to avoid the prospect of litigation. For instance, the Martek Petition requested that the FDA issue a statement that mercury counteracts the beneficial effects of EPA and DHA omega-fatty acids on cardiovascular health, but the FDA rejected the request because the scientific evidence on the subject was inconclusive. FDA Martek Petition Denial at 29. The FDA, however, does not face the prospect of ruinous lawsuits over failure to warn. Seafood suppliers, on the other hand, do face such potential lawsuits and would likely place

warnings about specific risks from consuming fish and shellfish that are not supported by science, but could be asserted in defense of future lawsuits. False or unsubstantiated warnings will only further deter fish consumption.

This places the seafood industry in an untenable position. As discussed in Tri-Union's Petition (at 22-26), Section 403 of the FDCA prohibits "misbranding," the furnishing of false and misleading information. The FDA has previously taken the position that the warnings required by California statute violate the FDCA. App. at 32a-34a (discussing letter from FDA Commissioner to California Attorney General); Tri-Union Petition at 22-24 (discussing same); *see also* Letter to Bill Lockyer, Attorney General of the State of California, from Lester M. Crawford, Commissioner of Food and Drugs dated Aug. 12, 2005, http://www.cfsan.fda.gov/~dms/fl-ltr65.html. Thus, complying with state warning requirements to avoid product liability actions could place seafood suppliers in an intractable conflict. They would face liability for not issuing warnings under state law, but potential action by the FDA for misbranding if they do issue warnings.

The Third Circuit dismissed this risk by stating that the FDA has taken no action against fish or shellfish sellers for misbranding. App. at 33a-35a. That conclusion ignores the obvious: until the Third Circuit opinion, seafood sellers did not face significant exposure from private lawsuits due to an alleged failure to warn, and *Dowhal*, which addressed similar

issues, had held that the FDA's decision to rely on advisories preempted state law warnings. Moreover, as the Third Circuit acknowledged, the FDA had issued a letter to the California Attorney General opining that state-law warnings about tuna would constitute false and misleading statements in violation of the FDCA. App. at 32a-34a. The FDA's position is clear that seafood producers and sellers face conflicting obligations if they try to comply with both state and federal law.

This Court can resolve the conflict by deciding whether the FDCA preempts state law and if compliance with state warning requirements would constitute "misbranding." Absent a grant of Tri-Union's Petition, the entire American seafood industry will be placed in the untenable position of choosing which liability – state or federal – they would prefer to incur. To avoid such an unworkable result, this Court should grant *certiorari*.

II. The Conflict Between The Third Circuit And California Supreme Court Creates Confusion About What Law Controls In Different Jurisdictions.

Tri-Union's Petition fully details the direct conflict that exists between the Third Circuit opinion and the California Supreme Court's opinion in *Dowhal*. The NFI will not repeat the specifics of this conflict, but the implications for the seafood industry are enormous.

Absent review, in some parts of the country, *e.g.*, California, state-law warnings have been declared preempted by the FDCA. Within the Third Circuit, however, state law warnings and product liability lawsuits based on failure to warn may be pursued. In the rest of the country, which law controls is unsettled. This will force seafood suppliers to litigate the preemptive effect of the FDCA in multiple jurisdictions, which is an unnecessary waste of judicial and the industry's resources, time, and money that could be avoided by a grant of *certiorari*.

CONCLUSION

For all of these reasons, and those discussed more fully in Tri-Union's Petition, the Third Circuit's opinion requires review by this Court. Given the significant risks the Third Circuit's opinion creates for the public health, and the tremendous burden it creates for the seafood industry, the Court should grant Tri-Union's Petition for a Writ of *Certiorari*.

Respectfully submitted,

Dated: February 17, 2009

AKIN GUMP STRAUSS HAUER & FELD LLP
REX S. HEINKE
WARREN E. CONNELLY
JESSICA M. WEISEL

Attorneys for Amicus Curiae, National Fishers Institute